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**Follow-Up  
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REGISTRANT'S NAME ReGen Therapeutics Plc

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**PROCESSED**

\*\*FORMER NAME \_\_\_\_\_

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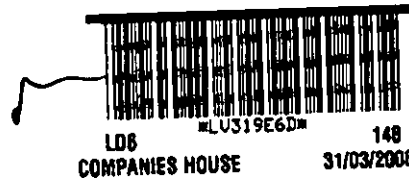
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**ReGen Therapeutics Plc**

**Report and Financial Statements**

**Year Ended**

**31 December 2005**



**BDO**

**BDO Stoy Hayward**  
Chartered Accountants

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**Directors**

P W C Lomax	(Executive Chairman)
K B Corbin	(Channel Islands) (Non Executive Deputy Chairman)
N A C Lott	(Finance Director)
M J Small	(New Projects Director)
T S Shilton	(Development Director)
P R Garrod	(Non Executive Director)

**Secretary and registered office** N A C Lott, 8 Baker Street, London, W1U 3LL.

**Company number** 3508592

**Business address** Suite 406, Langham House, 29-30 Margaret Street, London, W1W 8SA.

**Auditors** BDO Stoy Hayward LLP, 8 Baker Street, London, W1U 3LL.

**Nominated advisor** Nabarro Wells & Co Limited, Saddlers House, Gutter Lane, Cheapside, London, EC2V 6HS.

**Broker** J M Finn & Co, Salisbury House, London Wall, London, EC2M 5TA.

**Legal Advisors** Wilmer Cutler Pickering Hale and Dorr LLP, Alder Castle, 10 Noble Street, London, EC2V 7QJ.

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Summary

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**Developing treatments for the management of cognitive decline and other neurologic disorders, rehabilitation after traumatic brain injury, and building a sustainable healthcare business**

ReGen Therapeutics Plc is developing the constituent peptides of Colostrinin™ complex as a treatment for Alzheimer's disease and other neurological diseases and conditions. It continues to develop Colostrinin™ as a nutraceutical for cognitive enhancement and discussions are ongoing with potential partners. The Company widened its scientific base in 2005 by taking out an option to acquire Sciencom Limited, a private company, which has filed a patent application for a new use for an existing drug, which has been shown to improve the rehabilitation of stroke and brain injury victims. This option was exercised and Sciencom was acquired in February 2006.

**HIGHLIGHTS OF 2005**

- The option to acquire Sciencom and its development of a new use for zolpidem represented a major move for the Company into a potential market worth \$4.3 billion.
- In March we announced that Pali Capital has started making a market in ReGen American Depositary Receipts (which represents ReGen shares) in the US.
- A successful £1.56m funding was completed in October.
- In June ReGen announced that it had successfully defined the production process for Colostrinin™ at industrial scale.
- In July ReGen announced that it had appointed J M Finn & Company as its Broker.
- Science Milestones:

February – the United States Patent and Trademark Office has granted two patents regarding Colostrinin™: 1) US Patent No. 6,852,685 for the use of Colostrinin™ and its constituent peptides as a promoter of neuronal cell differentiation, and 2) US Patent No. 6,852,700 for the use of Colostrinin™ as a medicament, particularly in the treatment of chronic disorders of the central nervous system and the immune system.

April – ReGen announced that Colostrinin™ and a nine amino acid synthetic homolog of a Colostrinin™ derived peptide showed neuroprotection in a cell line model of Parkinson's disease.

June – the peer reviewed journal 'Neuropeptides' published an article showing that Colostrinin™ can prevent the aggregation of beta amyloid – a toxic protein that builds up in the brains of Alzheimer's disease sufferers.

August – ReGen announced the grant of a US patent No. 6,903,068 on the use of Colostrinin™ and its constituent peptides to promote induction of cytokines. The induction of cytokines can modulate the immune response in patients with Alzheimer's disease.

September – the United States Patent and Trademark Office has granted patent No. 6,939,847 for the use of Colostrinin™ and its constituent peptides as oxidative stress regulators.

October – ReGen presented an important paper regarding the effects of Colostrinin™ on life span in mice at the 21st International Conference of Alzheimer's Disease International in Istanbul.

In 2005 ReGen progressed on the financial, scientific and commercial fronts.

## **FINANCIALS**

As expected ReGen reported an operating loss for the year of £2.26m an increase of 46% over the previous year. This reflected an increase in development spend of 63%, some of which is reflected in future and not actual payments this year, and the real rise in development spend was 33%. The results of our increased development spend in 2004 and 2005 are shown in our encouraging scientific development. The acquisition of Guildford Clinical Pharmacology Unit Limited (GCPUL) in October 2004 doubled the number of full time employees within the group but our close control of costs and reorganisation of GCPUL meant that the rise in non development spend was only 40%. We are pleased to report that GCPUL's order book now stands at £663,000 and this has been achieved since the beginning of January 2006.

Turning now to the balance sheet the dramatic drop in debtors is merely that last year we had cash due to us from our stockbroker, who had made a December 2004 Placing for us and this was not received until January 2005.

## **SCIENTIFIC DEVELOPMENT**

During the year we continued our long-term research contracts at the University of Texas Medical Branch (UTMB), Galveston, Texas, USA and Roswell Park Cancer Institute (RPCI), Buffalo, New York, USA. These collaborations produced three important publications during the year. In June 2005 the peer-reviewed journal *Neuropeptides* published an article showing that Colostrinin™ can prevent the aggregation of beta amyloid – a toxic protein that builds up in the brains of Alzheimer's disease sufferers. In October 2005 ReGen presented an article at the 2005 Alzheimer's Disease Conference which showed that Colostrinin™ increases lifespan of mouse cells predisposed to premature ageing. In November 2005 another peer reviewed article regarding Colostrinin™ driven neurite outgrowth was published in the *Cellular and Molecular Neurobiology* journal.

Furthermore the scientific background provided by our collaborators gave us three more granted patents during the year. In addition to covering the use of Colostrinin™ as a medicament, particularly in the treatment of chronic disorders of the central nervous system and the immune system, our patent portfolio claims have been enhanced by 1) the use of Colostrinin™ and its constituent peptides as a promoter of neuronal cell differentiation, 2) the use of Colostrinin™ and its constituent peptides to promote induction of cytokines, and 3) the use of Colostrinin™ and its constituent peptides as oxidative stress regulators.

In addition, a further study was carried out by Proximagen, which showed that Colostrinin™ and a synthetic homolog of a Colostrinin™ derived peptide showed neuroprotection in a cell line model of Parkinson's disease. This is very important, as, although we had theoretically predicted that Colostrinin™ and its constituent peptides should have activity in other CNS neurodegenerative diseases, this was the first independent observation of this effect.

We were pleased to welcome Professor Michael Stewart of the Open University, who had previously completed work for us, as a consultant to provide further long-term scientific advice.

## **COMMERCIAL DEVELOPMENT**

In March Pali Capital our US Investment Bank started making a market in ReGen shares in New York. This is a further step in the progress of accessing the US capital markets for the long-term development of the Company. In a further development in our funding we appointed JM Finn & Co as our broker in July and they successfully raised £1.56m for us in September.

Chairman's statement (*Continued*)

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As part of our development of Colostrinin™ as a nutraceutical in June we announced the successful definition of the production process for Colostrinin™ at industrial scale. We are now working to make this process fully compliant with the necessary standards of Good Manufacturing Practice (GMP). We are in advanced stages of licensing discussions with a US based partner, and are in less advanced discussions with several companies around the world.

Most important for the year was the option to acquire Sciencom Limited and its new use for zolpidem. On the 6 September it was announced that ReGen had entered into an exclusive option arrangement with Sciencom, a private company, which has discovered an important new use for zolpidem, a long established drug, currently marketed for the treatment of insomnia. A patent application has been filed to cover this new use. Following the success of the feasibility study Sciencom was acquired by us in February 2006.

The clinical effect discovered in a number of 'open' clinical case observations is that zolpidem can normalise areas of brain dormancy secondary to a primary lesion in brain damage conditions. The clinical effects of this dormancy reversal have been restoration of consciousness, swallowing, co-ordination and motor function after stroke and traumatic brain injury. Given that stroke alone is the largest single cause of severe disability in England and Wales, with over 250,000 people being affected at any one time, the Company believes that this represents a significant medical and commercial opportunity.

This reversal of dormancy has been visualised by SPECT (Scanning Positron Emission Computed Tomography) brain scanning on dosing with zolpidem. The clinical effect is generally proportional to the size and position of the dormant area and correlates with drug levels in the brain/plasma. Whilst to date these effects have been achieved with existing formulations these are less than ideal for the new use, with sedation as a significant limiting factor. ReGen is therefore looking to develop new formulations to optimise the delivery of this important clinical benefit to a diverse range of patients.

ReGen is planning a Phase II clinical study on zolpidem, managed by our subsidiary CRO Guildford Clinical Pharmacology Unit Limited, which will be carried out in South Africa. In this study we will be comparing a novel formulation with a standard formulation in known zolpidem responders. We estimate the potential market size to be \$4.3 billion.

A new formulation for this indication could be licensed to another drug company for further development as early as 2007. Given the size of the market ReGen could obtain very significant milestone payments.

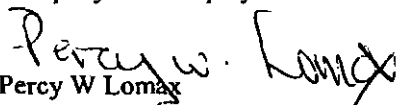
## SUMMARY

2005 was a solid year of development for ReGen and we believe that 2006 should show in commercial terms the fruits of our development to date. I am particularly excited in the short term about the prospects of zolpidem and in the longer term for the overall uses of Colostrinin™ and its constituent peptides in neurodegenerative diseases.

I would also like to thank our shareholders for their continued support throughout the year.

## MALCOLM BEVERIDGE

For personal reasons Malcolm Beveridge retired from the Board in April. He was crucial to the start of this Company and has played a role in it ever since.

  
Percy W Lomax  
Executive Chairman

**Executive Summary**

ReGen Therapeutics Plc was formed in 1998 to develop Colostrinin™ as a pharmaceutical for the treatment of Alzheimer's disease and other neurological disorders. To provide capital for this programme the company was floated on the Ofex market in December 1998 and on the Alternative Investment Market (AIM) of the London Stock Exchange in March 2000. In its public offerings and subsequent offerings the company has raised £15.2 million. We regard our ability to raise capital under difficult market conditions as crucial as it has enabled us to carry out our programme.

The company has used its money to achieve a number of significant milestones:

- ReGen's placebo controlled clinical trial of Colostrinin™ in 106 Alzheimer's sufferers over 30 weeks (RG-010) was finished in the Summer of 2002 and reached statistical significance with regard to its main clinical end-point of cognitive efficacy. The results of this were published in the peer reviewed Journal of Alzheimer's disease in February 2004.
- Colostrinin™ mode of action papers published.
- Colostrinin™ bio-assays developed to enable manufacturing scale-up.
- Colostrinin™ commercial production process defined.
- Ongoing science programmes, at The University of Texas Medical Branch, Galveston and Roswell Park Cancer Institute, Buffalo in the USA and at the Open University, Milton Keynes in the UK.
- Acquisition of Guildford Clinical Pharmacology Unit Limited in October 2004
- Acquisition of Sciencom Limited in February 2006.

In addition to manufacturing scale-up, the company's programme includes the following targets:

- To continue the development of pharmaceutical products based on the constituent peptides of Colostrinin™ for the treatment of Alzheimer's disease.
- To advance our general science further and identify new applications for Colostrinin™.
- To sign a deal with a co-development/licensing partner for the use of Colostrinin™ as a nutraceutical.
- To acquire further complementary businesses and projects.

**Background**

ReGen Therapeutics Plc was formed in 1998 to undertake the development of Colostrinin™, as a pharmaceutical for the treatment of Alzheimer's disease and other neurological disorders. Colostrinin™ is a proline-rich polypeptide complex developed from colostrum, mammals' first milk after the birth of an offspring and which is widely recognised for its immune properties.

ReGen acquired the intellectual property rights for Colostrinin™ from the Ludwik Hirszfeld Institute of Immunology & Experimental Therapy in Wroclaw, Poland that had been carrying out tests on patients for a number of years with apparent success.

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\* I Bolodgh et al, Journal of Molecular Neuroscience (2003), 20, 125-134; A.Bacsi et al, Cellular and Molecular Neurobiology (2005), 25, 1123-1139; D. Schuster et al, Neuropeptides (2005), 39,419-26

Operational review (*Continued*)

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ReGen made a decision to conduct initial patient trials in Poland as the authorities there were satisfied as to the safety of the drug following trials in Poland between 1995 and 1998. The largest and most robust of these, a study showing that Colostrinin™ was more effective than placebo and organic selenium and was well-tolerated, was published in 1999.\*\*

ReGen's placebo-controlled clinical trial on 106 Alzheimer's sufferers over 30 weeks (RG-010) was completed in the summer of 2002 and the results demonstrated efficacy in a significant proportion of patients treated, with no safety concerns. A peer reviewed manuscript detailing the full results of the study was published in the February 2004 edition of the Journal of Alzheimer's Disease \*\*\*.

Key results of the study were:

- Approximately 40% of patients on Colostrinin™ were stabilised or improved after 15 weeks of therapy, based on an Analysis of Overall Response.
- 33% of patients continued to show stabilisation or improvement after 30 weeks of treatment, although levels of benefit were slightly higher at the 15-week stage of the trial.
- Statistical significance achieved with regard to the primary measure of efficacy – ADAS cog (a measure of cognitive/memory function) and the secondary endpoint Independent Activities of Daily Living (IADL).
- Efficacy demonstrated in both mild and moderate symptom groups as measured by ADAS cog, with greatest effects seen in earlier stages of the disease.
- No drug-related serious adverse events or safety concerns were observed during the trial.

Following completion of this trial ReGen has been undertaking an extensive scientific development programme, much of it in collaboration with the University of Texas Medical Branch.

Key areas of activity have focused on developing a greater understanding of the mode of action of Colostrinin™ and its constituent peptides, which in turn has enabled development of bio-assays and the identification of functional (in-vivo) models.

During our discussions in 2004 with potential pharmaceutical and nutraceutical licensing partners, it became apparent to us that a product such as Colostrinin™ is more commercially attractive as a nutraceutical. We therefore have focussed on producing Colostrinin™ as a nutraceutical product and we have ongoing discussions with a number of potential partners.

Our scientific evidence, taken together with the publication of the findings of our clinical trial RG-010 in the peer reviewed Journal of Alzheimer's Disease, gives us confidence in the activity of Colostrinin™ in Alzheimer's disease. Thus we are in the process of characterizing the compounds constituent peptides, in the belief that this will lead to the development of a classical small molecular weight pharmaceutical product with a biological activity similar to or exceeding that of Colostrinin™. In fact, one of the constituent peptides, a nine amino-acid peptide, has been already identified, synthesized and proved to facilitate learning and memory in a rat model. (Subsequently, another nine amino-acid residue peptide has been shown to be neuroprotective in an in-vitro model predictive of activity in Parkinson's disease). We would stress that there is still no adequate treatment for Alzheimer's disease and that the leading current product has sales of over \$1 billion.

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\*\* J Leszek et al (1999), *Archivum Immunologiae et Therapiae Experimentalis* (Archives of Immunology and Experimental Therapy), 47, 377-385

\*\*\*A Bilikiewicz and W Gaus (2004), *Journal of Alzheimer's Disease*, 6, 17-26



### **Colostrinin™ Science Programme**

Colostrinin™ was first isolated from ovine colostrum and characterised as a proline-rich polypeptide (Janusz 1974). Colostrinin™ has been shown to be an immunoregulator that may induce maturation and differentiation of murine thymocytes. Also, it was demonstrated that Colostrinin™, and its active nonapeptide fragment (NP), obtained after proteolytic digestion, are inducers of IFN gamma and TNF alpha in the peripheral blood lymphocytes.

Details on the potential mode of action of Colostrinin™ were first presented at the 18<sup>th</sup> International Conference on Alzheimer's disease in Barcelona, Spain in October 2002. This work has since been published in the Journal of Molecular Neuroscience.

This showed that Colostrinin™ reduces the abundance of 4HNE-protein adducts, reduces intracellular levels of reactive oxygen species, inhibits 4HNE-mediated glutathione (GSH) depletion (important for maintenance of cellular red-ox status, metabolism and enzyme regulation) and inhibits 4HNE-induced activation of p53 protein and c-Jun NH2-terminal kinase enzymes (both involved in the process of apoptosis – programmed cell death).

#### **Four major scientific announcements were made during 2004.**

In May 2004 at the 14<sup>th</sup> Alzheimer Europe Conference scientists presented two papers: in one they showed that Colostrinin™ can prevent the aggregation of beta amyloid and reduce its toxic effect on neuroblastoma cells and in another one they showed that Colostrinin™ can block the proliferation and promote the differentiation of primary cells into neuronal cells.

In July 2004 at the 9<sup>th</sup> International Conference on Alzheimer's Disease and Related Disorders scientists reported that the neuroprotective effects of Colostrinin™ can be due, in part, to a decrease in beta amyloid-induced apoptosis.

Also in the same month, at the Federation of European Neurological Societies meeting it was reported that Colostrinin™ was able to enhance memory when compared with control saline injections in young chicks.

Finally, in October 2004 at The Society for Neuroscience meeting, the same scientists, again in the chick model, showed that pre-treatment with Colostrinin™ can limit the memory impairment induced by beta amyloid, a toxic protein involved in the pathology of Alzheimer's disease. Bovine sourced Colostrinin™ made by ReGen's new production process was shown to have the same activity profile as the ovine-sourced material as used in clinical studies.

#### **In 2005 further scientific milestones were achieved:**

##### **Patents:**

In February the United States Patent and Trademark Office has granted two patents regarding Colostrinin™: 1) US Patent No. 6,852,685 for the use of Colostrinin™ and its constituent peptides as a promoter of neuronal cell differentiation, and 2) US Patent No. 6,852,700 for the use of Colostrinin™ as a medicament, particularly in the treatment of chronic disorders of the central nervous system and the immune system.

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In September – the United States Patent and Trademark Office has granted patent No. 6,939,847 for the use of Colostrinin™ and its constituent peptides as oxidative stress regulators.

**Scientific Studies:**

In April 2005 ReGen announced that Colostrinin™ and a nine amino acid synthetic homolog of a Colostrinin™ derived peptide showed neuroprotection in a cell line model of Parkinson's disease.

In June 2005 the peer-reviewed journal 'Neuropeptides' published an article showing that Colostrinin™ can prevent the aggregation of beta amyloid – a toxic protein that builds up in the brains of Alzheimer's disease sufferers.

In October ReGen presented an important paper regarding the effects of Colostrinin™ on life span in mice at the 21st International Conference of Alzheimer's Disease International in Istanbul.

The significance of this work is that it suggests several interrelated ways in which Colostrinin™, or more specifically its constituent peptides, might achieve its clinical activity:

- Reduction/prevention of oxidative stress
- Encouragement of neuronal cell production
- Reduction/prevention of apoptosis
- Reduction/prevention of beta amyloid aggregation
- Increase the life span of neuronal cells

Oxidative stress is a general term for the build-up of harmful reactive oxygen species (ROS) as a result of normal/abnormal cell metabolism. This age-related build-up gradually overwhelms the normal processes, in which ROS are neutralized, leading to the modification of important molecules (e.g. enzymes) and the impairment of their function, ultimately leading to disease. Oxidative stress has recently been implicated as a key feature in the development of many age-related disorders, including neurodegenerative diseases such as Alzheimer's disease and Parkinson's disease or multiple sclerosis. In 2005 for the first time we showed activity of Colostrinin™ and a Colostrinin™ derived peptide in a cell model predictive of Parkinson's disease. We are investigating this further.

Apoptosis, known as programmed cell death, is the mechanism by which cells are caused to die when they reach the end of their life expectancy. However, premature apoptosis is often triggered by many pathological conditions including inflammation. In Alzheimer's disease, a particular example of brain inflammation, apoptosis is an important factor in progression of the disease.

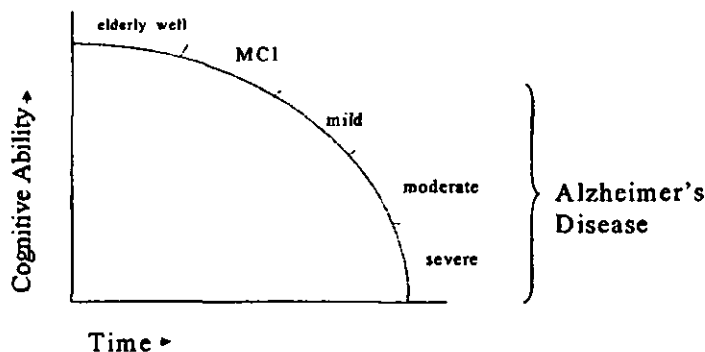
Alzheimer's disease is characterised by the accumulation of abnormal protein fibrils, including senile plaques, causing selective neuronal loss in the central nervous system. The primary components of senile plaques are insoluble aggregates of a peptide called amyloid beta. In addition, an abnormally high level of iron is witnessed in the brains of Alzheimer's disease patients. This is thought to stimulate oxidative stress in the brain, giving rise to free radicals which then go on to damage cells and cause subsequent brain inflammation.

**Colostrinin™ as a Nutraceutical**

As we have already said our development programme for Colostrinin™ is now focussed on developing it as a nutraceutical. Based on discussions with potential partners this could be as a stand-alone product or as part of a range of supplements for 'maintenance of healthy mental function' in the vast and increasing aged population at risk of cognitive decline. We are currently in advanced discussions with a potential American partner, and in less advanced discussions with other potential partners in the rest of the world.

## Business Opportunity

Cognitive decline in the elderly can be viewed as a progressive disease:



Most attempts at pharmaceutical intervention have targeted mild and moderate Alzheimer's disease, but a product that treated people with Mild Cognitive Impairment (MCI) or delayed their progression into and through this phase would have a large impact on the health of the elderly. We believe that this population is best accessed through nutraceutical products and, based on its natural source and the clinical results to date, Colostrinin™ has the profile to address this market.

Incidence and prevalence of age-related neurodegenerative disorders, including MCI and Alzheimer's disease, is increasing worldwide as people live longer. The prevalence of such disorders increases from one percent of the population in their early sixties to 25-50 percent in their late eighties. In 2001, 20 million people worldwide suffered from Alzheimer's disease and this is estimated to reach 40 million by 2025.

By 2009 the demand for anti-ageing nutraceutical products and services is predicted to reach around \$72 billion in the US. Active ingredients in anti-ageing pharmaceuticals will continue to comprise the largest segment of anti-ageing product chemicals, accounting for more than one quarter of such compounds. Neurological agents for the treatment of Alzheimer's disease and other age-related neurodegenerative disorders are expected to record robust growth, supported by medical advances. The anti ageing study that we reported on in 2005 is helpful in gaining acceptance for Colostrinin™ in this field.

Colostrinin™, a colostrum-derived complex of proline-rich polypeptides, has been shown to have potential benefit for the treatment of age related neurodegenerative disorders including Alzheimer's disease. Colostrinin™ potentially falls into the disease-modifying category because of its antioxidant effect and prevention of aggregation of  $\beta$ -amyloid peptides, which are both implicated in Alzheimer's disease. It has been given to over 150 patients with consistent evidence of efficacy and no safety concerns.

So far no therapeutic approach has halted disease progression convincingly. Therefore, Colostrinin™ has the potential to be one of the major products to succeed in this expanding market place as it could be taken prophylactically by otherwise healthy elderly people who may be at risk from developing Alzheimer's disease merely because of their increasing age.

### **About Alzheimer's disease (Source Alzheimer's Disease International)**

Alzheimer's disease is the most common cause of dementia. Dementia is a collective name for progressive degenerative brain syndrome, which affects memory, thinking, behaviour and emotion.

Symptoms may include:

- loss of memory
- difficulty in finding the right words or understanding what people are saying
- difficulty in performing previously routine tasks, and
- personality and mood changes.

There are currently an estimated 18 million people in the world with dementia. 66% of people with dementia live in developing countries.

There is no cure for Alzheimer's disease or for most other causes of dementia. However, many of the problems associated with dementia such as restlessness and depression can be treated. It may also be possible, especially in the early stages of dementia, to improve someone's memory with medication. There is an immense amount of research into new drug treatments for Alzheimer's disease and the other dementias.

Recent developments have been in the form of a group of drugs known as cholinesterase inhibitors or anti-cholinesterase drugs. These drugs work by reducing the breakdown of acetylcholine in the brain. Acetylcholine is a chemical substance that occurs naturally in the brain and enables nerve cells in the brain to pass messages to each other. Research has shown that many people with Alzheimer's disease have a reduced amount of acetylcholine, and it is thought that the loss of this chemical may result in deterioration of memory. Unfortunately this class of drugs has a number of side effects which may include diarrhoea, nausea, insomnia, fatigue and loss of appetite. These drugs are not a cure, and may only stabilise some of the symptoms of early to mid stage Alzheimer's disease for a limited period of time. The same concept has been tested with acetylcholine boosters. The objective here is not to inhibit acetylcholinesterase, but to induce the production of acetylcholine.

### **Other potential uses for Colostrinin™**

A proteomics screen with Colostrinin™ has shown that it has the ability to upregulate certain proteins in vitro. This confirms that active principles within Colostrinin™ are able to activate specific genes and direct the synthesis of very important proteins. This line of reasoning has been given further encouragement by a study reported in April 2005 that Colostrinin™ and a nine amino acid synthetic homolog of a Colostrinin™ derived peptide showed neuroprotection in a cell line model of Parkinson's disease. We believe we may be able to identify further new potential disease targets and uses for Colostrinin™, its constituent peptides or small molecular weight substances based on their activity. Further work to clarify this is now ongoing.

We are also investigating the possibility of using Colostrinin™ as a veterinary nutraceutical.

### **Sciencom – zolpidem a potential new use**

On the 6 September it was announced that ReGen had entered into an exclusive option arrangement with Sciencom a private company, which has discovered an important new use for zolpidem, a long established drug, currently marketed for the treatment of insomnia. A patent application has been filed to cover this new use. Following the success of the feasibility study Sciencom was acquired outright in February 2006.

The clinical effect discovered in a number of 'open' clinical case observations is that zolpidem can normalise areas of brain dormancy secondary to a primary lesion in brain damage conditions. The clinical effects of this dormancy reversal have been restoration of consciousness, swallowing, co-ordination and motor function after stroke and traumatic brain injury. Given that stroke alone is the largest single cause of severe disability in England and Wales, with over 250,000 people being affected at any one time, the Company believes that this represents a significant medical and commercial opportunity.

This reversal of dormancy has been visualised by SPECT brain scanning on dosing with zolpidem. The clinical effect is generally proportional to the size and position of the dormant area and correlates with drug levels in the brain/plasma. Whilst to date these effects have been achieved with existing formulations these are less than ideal for the new use, with sedation as a significant limiting factor. ReGen is therefore looking to develop new formulations to optimise the delivery of this important clinical benefit to a diverse range of patients.

ReGen is planning a Phase II clinical study on zolpidem, managed by our subsidiary CRO Guildford Clinical Pharmacology Unit Limited, which will be carried out in South Africa. In this study we will be comparing a novel formulation with a standard formulation in known zolpidem responders. We estimate the potential market size to be \$4.3 billion.

#### **Guildford Clinical Pharmacology Unit Limited**

In October 2004 the Company acquired Guildford Clinical Pharmacology Unit Limited (GCPUL), a Contract Research Organisation based in Surrey, England.

GCPUL provides a high quality service in performing clinical trials for the pharmaceutical and biotechnology industry, using its associations with the Royal Surrey County Hospital and the University of Surrey. Over the past ten years GCPUL has established a reputation for delivering quality research to its clients and has successfully completed studies embracing a wide spectrum of therapeutic areas, encompassing First-Dose to Man through to Phase II studies.

As a small business privately financed by two individuals GCPUL has suffered from a lack of funds to develop its business, particularly in marketing and providing a stand alone bed unit. As the funds required were comparatively small and the potential rewards high, the ReGen Board identified this as a prime attraction in acquiring GCPUL.

The new marketing activities have already started and will be ongoing for the foreseeable future, supported by an advertising campaign in the pharmaceutical press. The nature of the contract research sector is that new business can take many weeks, or more usually months, to negotiate to a point where a contract is signed and preparations for the trial commence. However we continue to have confidence in our ability to build the Company into a profitable revenue earner for the Group.

#### **American Depositary Receipt (ADR) Programme**

Looking to the future development of the Company, we have established an ADR programme in the US. This is commercially relevant as we carry out research, development and manufacturing in the US and 62% of central nervous system pharmaceutical sales are in the US, which is also the most developed nutraceutical market in the world. On the financial side, the US is by far the largest capital market, particularly for biotech, and in consequence we believe that shareholder value will be enhanced by entering into this market. Pali Capital started making a market in ReGen ADR's in March 2005.

**Percy Lomax BSc (Econ) FSI**  
(Executive Chairman)

Percy Lomax joined the commercial intelligence department of Allen & Hanbury's, part of the Glaxo Group, in July 1967 and has been involved in the drug industry since then, either as an adviser or an employee. He was stockbroker in August 1987 to the flotation of Medirace Plc, which became Medeva Plc. As a healthcare analyst at Robert Fleming and Co he worked on the second fund raising for Wellcome in 1992. In 1995 he co-founded PolyMasc Pharmaceuticals Plc and was instrumental in its flotation in December of that year. In 1996 he was responsible for the rescue rights issue of Proteus Plc and the flotation of Oxford BioMedica plc.

**Norman Lott BSc ACA**  
(Finance Director and Company Secretary)

Norman Lott qualified as a chartered accountant in 1980 with Ernst & Whinney and joined Peat Marwick Mitchell & Company in their Hong Kong office in 1981. From 1984 onwards he held a number of senior financial positions in commerce and industry before joining Tiger Books International Plc in 1993 as finance director and was subsequently appointed as deputy managing director. He joined the Board of ReGen as Finance Director in June 1999.

**Keith Corbin ACIB**  
(Non-executive Deputy Chairman)

Keith Corbin is a non-executive Director of ReGen and has served on the Board of the Company since 1998. For the last twenty-five years, he has served as the Group Managing Director and Chairman of financial services businesses in various parts of the World. From 1979 to 1997, he was the Group Managing Director of Havelet Holdings Limited and is currently the Chairman of an independent financial services business, Nerine Trust Company Limited, with operations in Guernsey and the British Virgin Islands. He serves as a non-executive director on various boards. He is an associate of the Chartered Institute of Bankers and a member of the Society of Trust and Estate Practitioners.

**Martin Small**  
(New Projects Director)

Martin Small entered the international commodity trade in 1982, initially trading sugar in the Far Eastern and Middle Eastern markets, before moving to commodity broking in 1985. Working with clients in the Far East and West Africa, he gained an extensive knowledge of the oilseed industry and, in particular, the Hong Kong edible oil market. From the beginning of 1991, Martin developed various industrial business ventures in Scandinavia and Poland. In 1996 he met Jerzy Georgiades and learned of his work on a prospective therapy for Alzheimer's disease in Poland. The work with Dr Georgiades led to their founding of The Georgiades Foundation Ltd and the acquisition of the ownership and development rights to Colostrinin™ from its original Polish investors in October 1997. Following the sale of The Georgiades Foundation Limited to ReGen in October 1998, Martin joined ReGen as General Manager and was appointed to the Board as New Projects Director on 10 December 2002.

**Timothy Shilton BSc Hons**  
(Development Director)

Tim Shilton has been involved in the pharmaceutical industry for over 20 years. After completing his degree at Surrey University in 1979 Tim joined the Regulatory Affairs Department at Wellcome, where he was specifically involved in product registration and licensing. He later transferred to International Strategic Marketing/New Products, where he was part of the team responsible for establishing Wellcome as the market leader in antivirals with Zovirax (aciclovir) and Retrovir (AZT). After leaving Wellcome in 1995 Tim consulted for various pharmaceutical and healthcare communications companies, before joining Phairson Medical in 1996, as product development and marketing director. Tim joined ReGen in November 2000 as Development Manager and was appointed to the Board as Development Director on 10th December 2002.

**Dr Peter Garrod BDS, LDS**  
(Non Executive Director)

Dr Garrod was educated at the London Hospital, part of the University of London. He graduated with a BDS and is a LDS of the Royal College of Surgeons. He has been the Senior Partner of the Bower Dental Centre, which specialises in advanced dental cosmetic surgery, for the last 18 years.

**Professor Marian L Kruzel PhD**  
(Scientific Consultant)

Professor Marian Kruzel is a faculty member of the Department of Integrative Biology and Pharmacology, The University of Texas, Medical School at Houston. He is an internationally recognized immunologist with an established interest and expertise in inflammation and age-related pathophysiology. He is the recipient of numerous grants and a participant in NIH funded projects. Also, he serves as a reviewer on several scientific journals, including *Clinical and Experimental Immunology* and *Cellular and Molecular Biology Letter*. Recently, he has been elected as an Associate Editor of the *Journal of Experimental Therapeutics and Oncology*. In 1999 Prof. Kruzel founded PharmaReview Corporation, a consulting firm that provides guidance to bio-medical research companies in various project design and development of clinical protocols. He is the former chairman of the board of Cancer Coalition of America. Through a consultancy agreement with the Company Prof. Kruzel is responsible to the Board for scientific research and development and management of the scientific aspects of future clinical development on behalf of the Company.

The directors present their report together with the audited financial statements for the year ended 31 December 2005.

**Results and dividends**

The profit and loss account is set out on page 18 and shows the loss for the year.

The directors do not recommend the payment of an ordinary dividend (2004 - £Nil).

**Principal activities, trading review and future developments**

The principal activity of the Group was drug development and ancillary services, and conducting pharmacokinetic and pharmacodynamic research.

A review of the business and future developments is contained in the Chairman's statement on pages 2 and 3.

**Policy of the payment of creditors**

Amounts due to suppliers are settled promptly within their terms of payment except in cases of dispute.

The number of days purchases of the Company represented by trade creditors at 31 December 2005 was 39 (2004 - 51).

**Corporate governance**

The directors acknowledge the importance of the revised Combined Code issued by the Financial Reporting Council (2003 FRC Code) in July 2003 and intend to apply the Code as appropriate to the Company given its size and nature.

A remuneration committee has been established and is comprised of 2 non-executive directors. It reviews the performance of executive directors and senior executives and recommends the scale and structure of their remuneration and reviews the basis of their service agreements with due regard to the interests of shareholders. No director participates in decisions concerning his own remuneration.

An audit committee has been established and comprises the non-executive directors.

**Research and development**

All expenditure incurred in respect of the development of Colostrinin™ has been charged to the profit and loss account in accordance with the Group's stated accounting policy.



### Charitable Donations

The Company donated £350 (2004 - £Nil) to the Alzheimer's Society during the year.

### Post balance sheet event

On 14 February 2006 the Group acquired Sciencom Limited. Further details are given in note 26.

### Directors

The directors of the Company during the year were:

P W C Lomax  
M C R Beveridge – Non-executive (resigned 26 April 2005)  
K B Corbin – Non-executive  
N A C Lott  
M J Small  
T S Shilton  
P R Garrod – Non-executive (appointed 8 March 2005)

### Directors' interests

The directors' interests in the shares of the Company at the year end were:

	Ordinary shares of 0.1p each		Deferred shares of 4.9p each	
	31 December 2005	31 December 2004	31 December 2005	31 December 2004
P W C Lomax	2,282,069	1,782,069	1,448,736	1,448,736
K B Corbin	105,000	105,000	105,000	105,000
N A C Lott	182,000	32,000	32,000	32,000
M J Small	2,248,736	1,348,736	1,348,736	1,348,736
T S Shilton	500,000	-	-	-
P R Garrod	61,250,000	-	3,715,000	-

Share options held by directors are disclosed in note 7 to the financial statements.

**Directors' responsibilities**

Company law requires the directors to prepare financial statements for each financial year, which give a true and fair view of the state of affairs of the Company and Group and of the profit or loss of the Group for that year. In preparing those financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable and prudent;
- state whether applicable accounting standards have been followed, subject to any material departure disclosed and explained in the financial statements; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the Group will continue in business.

The directors are responsible for keeping proper accounting records which disclose with reasonable accuracy at any time the financial position of the Company and to enable them to ensure that the financial statements comply with the Companies Act 1985. They are also responsible for safeguarding the assets of the Group and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

**Auditors**

BDO Stoy Hayward LLP have expressed their willingness to continue in office and a resolution to re-appoint them will be proposed at the annual general meeting.

**By order of the Board**

N Lott



**Secretary**

**To the shareholders of ReGen Therapeutics Plc**

We have audited the group and parent company financial statements of ReGen Therapeutics Plc for the year ended 31 December 2005 which comprise the group profit and loss account, the group and company balance sheets, the group cash flow statement and the related notes. These financial statements have been prepared under the accounting policies set out therein.

*Respective responsibilities of directors and auditors*

As described in the Statement of Directors' Responsibilities the company's directors are responsible for the preparation of the financial statements in accordance with applicable law and United Kingdom Accounting Standards (United Kingdom Generally Accepted Accounting Practice).

Our responsibility is to audit the financial statements in accordance with relevant legal and regulatory requirements and International Standards on Auditing (UK and Ireland).

We report to you our opinion as to whether the financial statements give a true and fair view and are properly prepared in accordance with the Companies Act 1985. We also report to you if, in our opinion, the Directors' Report is not consistent with the financial statements, if the company has not kept proper accounting records, if we have not received all the information and explanations we require for our audit, or if information specified by law regarding directors' remuneration and other transactions is not disclosed.

We read other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. The other information comprises the Directors' Report, the Chairman's Statement and the Operational Review. We consider the implications for our report if we become aware of any apparent misstatements or material inconsistencies with the financial statements. Our responsibilities do not extend to any other information.

Our report has been prepared pursuant to the requirements of the Companies Act 1985 and for no other purpose. No person is entitled to rely on this report unless such a person is a person entitled to rely upon this report by virtue of and for the purpose of the Companies Act 1985 or has been expressly authorised to do so by our prior written consent. Save as above, we do not accept responsibility for this report to any other person or for any other purpose and we hereby expressly disclaim any and all such liability.

*Basis of audit opinion*

We conducted our audit in accordance with International Standards on Auditing (UK and Ireland) issued by the Auditing Practices Board. An audit includes examination, on a test basis, of evidence relevant to the amounts and disclosures in the financial statements. It also includes an assessment of the significant estimates and judgments made by the directors in the preparation of the financial statements, and of whether the accounting policies are appropriate to the company's circumstances, consistently applied and adequately disclosed.

We planned and performed our audit so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or other irregularity or error. In forming our opinion we also evaluated the overall adequacy of the presentation of information in the financial statements.

*Fundamental uncertainty – going concern*

In forming our opinion, we have considered the adequacy of the disclosures made in note 25 of the financial statements concerning the uncertainty as to the outcome of future fund-raising. In view of the significance of this matter we consider that it should be drawn to your attention. Our opinion is not qualified in this respect.

*Opinion*

In our opinion the financial statements:

- give a true and fair view, in accordance with United Kingdom Generally Accepted Accounting Practice, of the state of the group's and the parent company's affairs as at 31 December 2005 and of the group's loss for the year then ended; and
- have been properly prepared in accordance with the Companies Act 1985.

*BDO Stoy Hayward LLP*

**BDO STOY HAYWARD LLP**

*Chartered Accountants  
and Registered Auditors  
London*

16 March 2006

Consolidated profit and loss account for the year ended 31 December 2005

	Note	2005 £	2004 £
<b>Turnover</b>		115,657	98,794
Cost of sales		39,713	44,665
		<hr/>	<hr/>
<b>Gross profit</b>		75,944	54,129
<b>Administrative costs</b>			
Development costs		745,012	456,566
Other		1,496,465	1,063,446
Goodwill amortisation		94,036	77,748
		<hr/>	<hr/>
		2,335,513	1,597,760
<b>Operating loss</b>	3	(2,259,569)	(1,543,631)
Interest receivable		47,139	46,126
Interest payable	4	(10,216)	(4,723)
		<hr/>	<hr/>
<b>Loss on ordinary activities before taxation</b>		(2,222,646)	(1,502,228)
Taxation on loss on ordinary activities	8	81,930	114,202
		<hr/>	<hr/>
<b>Loss on ordinary activities after taxation</b>	18	(2,140,716)	(1,388,026)
		<hr/>	<hr/>
Basic and diluted loss per share	9	(0.56p)	(0.49p)

All amounts relate to continuing activities.

All recognised gains and losses are included in the profit and loss account.

The notes on pages 22 to 39 form part of these financial statements.

ReGen Therapeutics Plc

Consolidated balance sheet at 31 December 2005

	Note	2005 £	2005 £	2004 (restated) £	2004 (restated) £
<b>Fixed assets</b>					
Intangible assets	10		2,166,765		2,190,130
Tangible assets	11		21,180		18,498
			<u>2,187,945</u>		<u>2,208,628</u>
<b>Current assets</b>					
Stocks	13	4,276		500	
Debtors	14	309,419		1,163,549	
Cash at bank and in hand		941,503		771,185	
		<u>1,255,198</u>		<u>1,935,234</u>	
<b>Creditors: amounts falling due within one year</b>	15	618,477		601,068	
<b>Net current assets</b>			<u>636,721</u>		<u>1,334,166</u>
<b>Total assets less current liabilities</b>			<u>2,824,666</u>		<u>3,542,794</u>
<b>Capital and reserves</b>					
Called up share capital	17		5,797,689		5,639,868
Share premium	18		10,437,948		9,173,181
Other reserves	18		242,308		242,308
Profit and loss account	18		(13,653,279)		(11,512,563)
<b>Equity shareholders' funds</b>	19		<u>2,824,666</u>		<u>3,542,794</u>

The financial statements were approved by the Board and authorised for issue on 16 March 2006

P W C Lomax  
Director

The notes on pages 22 to 39 form part of these financial statements.

**ReGen Therapeutics Plc**
**Company balance sheet at 31 December 2005**

	Note	2005 £	2005 £	2004 £	2004 £
<b>Fixed assets</b>					
Intangible assets	10		648,751		573,677
Tangible assets	11		4,714		4,493
Investments	12		3,018,527		2,939,671
			<hr/>		<hr/>
			3,671,992		3,517,841
<b>Current assets</b>					
Debtors	14	572,742		1,044,007	
Cash at bank and in hand		940,942		770,317	
		<hr/>		<hr/>	
		1,513,684		1,814,324	
<b>Creditors: amounts falling due within one year</b>	15	302,456		307,511	
		<hr/>		<hr/>	
<b>Net current assets</b>			1,211,228		1,506,813
			<hr/>		<hr/>
<b>Total assets less current liabilities</b>			4,883,220		5,024,654
			<hr/>		<hr/>
<b>Capital and reserves</b>					
Called up share capital	17		5,797,689		5,639,868
Share premium	18		10,437,948		9,173,181
Profit and loss account	18		(11,352,417)		(9,788,395)
			<hr/>		<hr/>
<b>Equity shareholders' funds</b>	19		4,883,220		5,024,654
			<hr/>		<hr/>

The financial statements were approved by the Board and authorised for issue on 16 March 2006

*P W C Lomax*  
P W C Lomax  
Director

The notes on pages 22 to 39 form part of these financial statements.

## Consolidated cash flow statement for the year ended 31 December 2005

	Note	2005 £	2005 £	2004 £	2004 £
<b>Net cash outflow from operating activities</b>	20		(1,263,628)		(1,760,901)
<b>Returns on investments and servicing of finance</b>					
Interest received		47,139		46,126	
Interest paid		(10,216)		(4,723)	
			36,923		41,403
<b>Taxation</b>			104,202		-
<b>Capital expenditure and financial investment</b>					
Payments to acquire tangible fixed assets		(10,814)		(4,346)	
Payments to acquire intangible fixed assets		(95,754)		(66,234)	
			(106,568)		(70,580)
<b>Acquisitions</b>					
Purchase of a subsidiary undertaking:					
Acquisition expenses		-		(73,050)	
Net overdraft acquired with subsidiary		-		(115,234)	
			-		(188,284)
<b>Net cash outflow before management of liquid resources and financing</b>			(1,229,071)		(1,978,362)
<b>Management of liquid resources</b>					
(Increase)/decrease in short term deposits		(175,095)		206,058	
			(175,095)		206,058
<b>Financing</b>					
Proceeds from shares issued for cash		1,556,000		1,748,000	
Expenses paid on share issue		(133,412)		(95,254)	
			1,422,588		1,652,746
<b>Increase/(decrease) in cash</b>	21		18,422		(119,558)

The notes on pages 22 to 39 form part of these financial statements.



## 1 Accounting policies

The financial statements have been prepared under the historical cost convention and are in accordance with applicable accounting standards. In preparing these financial statements the Group has adopted FRS 25 "Financial instruments: disclosure and presentation" for the first time. The adoption of this standard represents a change in accounting policy and the comparative figures have been restated accordingly. Further details are given in note 27. The following principal accounting policies have been applied:

### *Basis of consolidation*

The consolidated financial statements incorporate the results of ReGen Therapeutics Plc and all subsidiary undertakings as at 31 December 2005, using the acquisition method of accounting. The results of subsidiary undertakings are included from the date of acquisition. Intra Group sales and profits are eliminated on consolidation.

### *Goodwill*

Goodwill arising on an acquisition of a subsidiary undertaking is the difference between the fair value of the consideration paid and the fair value of the assets and liabilities acquired. It is capitalised and written off in equal annual instalments over its estimated useful economic life of 20 years. Impairment tests on the carrying value of goodwill are undertaken:

- at the end of the first full financial year following acquisition
- in other periods if events or changes in circumstances indicate that the carrying value may not be recoverable.

### *Fixed Asset Investments*

Investments acquired in exchange for company shares are held at nominal value where the acquisition met merger relief conditions under S131 of the Companies Act 1985 plus the fair value of any other consideration. Other investments are stated at cost less any provision for impairment.

### *Turnover*

Turnover represents amounts invoiced during the year, exclusive of Value Added Tax.

### *Depreciation of tangible fixed assets*

Depreciation is provided to write off the cost, less residual values of all tangible fixed assets evenly over their expected useful lives. It is calculated at the following rate:

Office equipment - 25% per annum on cost

### *Work in Progress*

Work in progress is valued on the basis of direct costs plus attributable overheads based on normal levels of activity. Provision is made for any foreseeable losses where appropriate. No element of profit is included in the valuation of work in progress.

**1 Accounting policies (Continued)**

*Foreign currency*

Foreign currency transactions of individual companies are translated at the rates ruling when they occurred. Foreign currency monetary assets and liabilities are translated at the rates ruling at the balance sheet dates. Any differences are taken to the profit and loss account.

*Financial instruments*

In relation to the disclosures made in note 16:

- short-term debtors and creditors are not treated as financial assets or financial liabilities
- the Group does not hold or issue derivative financial instruments for trading purposes.

*Research and development*

Expenditure on pure and applied research and development costs are charged to the profit and loss account in the year in which it is incurred.

*Patents and trademarks*

Costs to obtain patent rights for the use of Colostrinin have been capitalised and will be amortised over 20 years, the expected useful life of the patent from the date the patent is granted.

*Deferred taxation*

Deferred tax balances are recognised in respect of all timing differences that have originated but not reversed by the balance sheet date except that the recognition of deferred tax assets is limited to the extent that the Company anticipates to make sufficient taxable profits in the future to absorb the reversal of the underlying timing differences.

Deferred tax balances are not discounted.

*Leased assets*

Where assets are financed by leasing agreements that give rights approximating to ownership (finance leases), the assets are treated as if they had been purchased outright. The amount capitalised is the present value of the minimum lease payments payable over the term of the lease. The corresponding leasing commitments are shown as amounts payable to the lessor. Depreciation on the relevant assets is charged to the profit and loss account.

Lease payments are analysed between capital and interest components. The interest element of the payment is charged to the profit and loss account over the period of the lease and is calculated so that it represents a constant proportion of the balances of capital repayments outstanding. The capital element reduces the amounts payable to the lessor.

All other leases are treated as operating leases. Their annual rentals are charged to the profit and loss account on a straight line basis over the term of the lease.

**1 Accounting policies (Continued)***Pension costs*

Contributions to individuals defined contribution pension schemes are charged to the profit and loss account in the period in which they become payable.

*Share based employee remuneration*

When shares and share options are granted to employees a charge is made to the Group profit and loss account and a reserve created in capital and reserves to record the intrinsic value of the awards in accordance with UITF Abstract 17 (revised 2003) 'Employee Share Schemes'.

*National Insurance on Share Options*

To the extent that the share price at the balance sheet date is greater than the exercise price on options granted under unapproved schemes after 19 May 2000, provision for any National Insurance contributions has been made based on the prevailing rate of National Insurance. The provision is accrued over the performance period attaching to the award.

*Liquid resources*

For the purposes of the cash flow statement, liquid resources are defined as current asset investments and short term deposits.

**2 Turnover**

All turnover relates to the Group's principal business activities and arises solely within the United Kingdom.

**3 Operating loss**

	2005 £	2004 £
This has been arrived at after charging:		
Depreciation of owned assets	8,132	4,947
Amortisation of goodwill	94,036	77,748
Amortisation of patent costs	25,083	14,712
Auditors' remuneration - audit fee - Group	35,000	34,000
- other services	18,965	23,961
Operating lease rentals - land and buildings	68,852	42,909
	<u>          </u>	<u>          </u>

Included within the Group audit fee is an amount of £20,000 (2004 - £19,000) in respect of the Company.

**4 Interest payable**

	2005	2004
	£	£
Bank interest	10,216	4,723

**5 Loss attributable to members of the parent company**

The Company has taken advantage of the exemption allowed under section 230 of the Companies Act 1985 and has not presented its own profit and loss account in these financial statements.

The Group loss for the year includes a loss after tax of £1,564,022 (2004 - £1,276,468), which is dealt with in the financial statements of the parent company.

**6 Employees**

Group	2005	2004
	£	£
Staff costs consist of:		
Wages and salaries	635,700	430,031
Social security costs	26,386	50,162
Other pension costs	6,366	-
	668,452	480,193

The average number of employees of the Group during the year, including directors, was as follows:

	Number	Number
Administration	12	7
Scientific	2	1
	14	8

6 Employees (Continued)

Company	2005 £	2004 £
Staff costs consist of:		
Wages and salaries	413,937	389,911
Social security costs	2,987	45,752
Other pension costs	-	-
	<u>416,924</u>	<u>435,663</u>

The average number of employees of the Company during the year, including directors, was as follows:

	Number	Number
Administration	6	6
Scientific	1	1
	<u>7</u>	<u>7</u>

7 Directors

	2005 £	2004 £
Directors' emoluments by individual:		
P W C Lomax	112,976	97,150
M C R Beveridge	9,900	28,004
K B Corbin	25,466	20,954
N A C Lott	76,228	70,148
M J Small	70,833	71,428
T S Shilton	80,982	82,703
P R Garrod	16,304	-
	<u>392,689</u>	<u>370,387</u>

## 7 Directors (Continued)

The share options of the directors at the year end under approved and unapproved share option schemes are set out below:

	At 1 January and 31 December 2005 Number	Exercise price	Date from which exercisable	Expiry date
P W C Lomax	1,500,000	6p	13 February 2004	13 February 2009
	400,000	6p	21 December 2004	21 December 2009
M C R Beveridge	400,000	6p	13 February 2004	13 February 2009
K B Corbin	150,000	28p	24 March 2002	23 March 2010
	350,000	6p	13 February 2004	13 February 2009
N A C Lott	150,000	28p	24 March 2002	23 March 2010
	750,000	6p	13 February 2004	13 February 2009
	150,000	6p	21 December 2004	21 December 2009
M J Small	150,000	12p	5 December 2002	4 December 2011
	900,000	6p	13 February 2004	13 February 2009
	100,000	6p	21 December 2004	21 December 2009
T S Shilton	150,000	12p	5 December 2002	4 December 2011
	600,000	6p	13 February 2004	13 February 2009
	200,000	6p	21 December 2004	21 December 2009

No options lapsed during the year. The market price of the shares at 31 December 2005 was 1.18p and the range during the financial year was 0.81p to 2.63p.

**8 Taxation**

	2005 £	2004 £
UK corporation tax credit in respect of current period	81,930	61,608
Overprovision in respect of prior years	-	52,594
	<u>81,930</u>	<u>114,202</u>
Total current tax credit	<u>81,930</u>	<u>114,202</u>

The Group has tax losses of approximately £10,000,000 (2004 - £8,600,000) for offset against future profits.

The tax for the year differs from the standard rate of corporation tax in the UK. The differences are explained below:

	2005 £	2004 £
Loss on ordinary activities before tax	2,222,646	1,502,228
	<u>2,222,646</u>	<u>1,502,228</u>
Loss on ordinary activities at the standard rate of corporation tax in the UK of 30% (2004 - 30%)	666,794	450,668
Effects of:		
Expenses not deductible for tax purposes	(43,207)	(52,187)
Enhanced relief tax research and development	51,206	38,505
Capital allowances for year in excess of depreciation	31,485	25,053
Unrelieved tax losses	(706,278)	(462,039)
Adjustment to tax for charge in respect of previous years	-	52,594
R & D tax credit refundable	81,930	61,608
	<u>81,930</u>	<u>114,202</u>
Current tax credit for the year	<u>81,930</u>	<u>114,202</u>

**9 Loss per share**

The basic loss per ordinary share has been calculated using the weighted average number of shares in issue during the relevant financial year. The weighted average number of equity shares in issue are 383,344,701 ordinary shares of 0.1p each and the loss is £2,140,716 (2004 - 280,747,760 ordinary shares of 0.1p each and a loss of £1,388,026).

The Company has instruments that could potentially dilute basic earnings per share in the future, but have not been included in the calculation of diluted earnings per share because they are antidilutive for the periods presented. These instruments are disclosed per notes 17 and 26.

**10 Intangible assets**

<b>Group</b>	<b>Goodwill £</b>	<b>Patent rights £</b>	<b>Trade marks £</b>	<b>Total £</b>
<i>Cost</i>				
At 1 January 2005	1,805,976	934,065	4,681	2,744,722
Additions	-	95,754	-	95,754
	<hr/>	<hr/>	<hr/>	<hr/>
At 31 December 2005	1,805,976	1,029,819	4,681	2,840,476
	<hr/>	<hr/>	<hr/>	<hr/>
<i>Amortisation</i>				
At 1 January 2005	524,687	29,905	-	554,592
Charge for the year	94,036	25,083	-	119,119
	<hr/>	<hr/>	<hr/>	<hr/>
At 31 December 2005	618,723	54,988	-	673,711
	<hr/>	<hr/>	<hr/>	<hr/>
<i>Net book value</i>				
At 31 December 2005	1,187,253	974,831	4,681	2,166,765
	<hr/>	<hr/>	<hr/>	<hr/>
At 31 December 2004	1,281,289	904,160	4,681	2,190,130
	<hr/>	<hr/>	<hr/>	<hr/>
<b>Company</b>				<b>Patent rights £</b>
<i>Cost</i>				
At 1 January 2005				589,719
Additions				91,048
				<hr/>
At 31 December 2005				680,767
				<hr/>
<i>Amortisation</i>				
At 1 January 2005				16,042
Charge for the year				15,974
				<hr/>
At 31 December 2005				32,016
				<hr/>
<i>Net book value</i>				
At 31 December 2005				648,751
				<hr/>
At 31 December 2004				573,677
				<hr/>



**11 Tangible assets**

<b>Group</b>	<b>Office equipment £</b>
<i>Cost</i>	
At 1 January 2005	127,686
Additions	10,814
	<hr/>
At 31 December 2005	<b>138,500</b>
	<hr/>
<i>Depreciation</i>	
At 1 January 2005	109,188
Charge for the year	8,132
	<hr/>
At 31 December 2005	<b>117,320</b>
	<hr/>
<i>Net book value</i>	
At 31 December 2005	<b>21,180</b>
	<hr/>
At 31 December 2004	<b>18,498</b>
	<hr/>

## 11 Tangible assets (Continued)

Company	Office equipment £
<i>Cost</i>	
At 1 January 2005	59,650
Additions	3,357
	<hr/>
At 31 December 2005	63,007
	<hr/>
<i>Depreciation</i>	
At 1 January 2005	55,157
Charge for the year	3,136
	<hr/>
At 31 December 2005	58,293
	<hr/>
<i>Net book value</i>	
At 31 December 2005	4,714
	<hr/>
At 31 December 2004	4,493
	<hr/>

12 Investments - Company

	Investments in subsidiary undertaking £	Loans to subsidiary undertakings £	Total £
At 1 January 2005 – at cost	1,505,029	1,434,642	2,939,671
Additions	-	78,856	78,856
	<hr/>	<hr/>	<hr/>
At 31 December 2005 – at cost	1,505,029	1,513,498	3,018,527
	<hr/>	<hr/>	<hr/>

The investments at 31 December 2005 represent a 100% investment in ReGen Polska, a 100% interest in the ordinary shares of Guildford Clinical Pharmacology Unit Limited, and a 100% interest in the ordinary 'A' shares of The Georgiades Foundation Limited and its wholly owned subsidiaries, ReGen Biotech Limited and Georgiades Biotech Limited. All of the above are unlisted companies.

Name	Country of registration	Nature of business
Guildford Clinical Pharmacology Unit Limited	Great Britain	Clinical Research
ReGen Biotech Limited *	Great Britain	Dietary supplement licensee
The Georgiades Foundation Limited	British Virgin Islands	Developer of Colostrinin
Georgiades Biotech Limited *	British Virgin Islands	Developer of Colostrinin
ReGen Polska	Poland	Developer of Colostrinin

\* Interest held indirectly via The Georgiades Foundation Limited.

The investment in The Georgiades Foundation Limited is as follows:

Class of share	Number of shares in issue	Percentage held
10c ordinary 'A' shares	22,100	100
10c deferred shares	6,852	58
	<hr/>	
	28,952	
	<hr/>	

The share capital of The Georgiades Foundation Limited is denominated in US dollars.

**13 Stocks**

	Group 2005 £	Group 2004 £	Company 2005 £	Company 2004 £
Work in progress	4,276	500	-	-

**14 Debtors**

	Group 2005 £	Group 2004 £	Company 2005 £	Company 2004 £
Amounts due from group undertakings	-	-	324,167	6,830
Trade debtors	34,532	53,646	-	-
Other debtors	56,580	100,829	33,911	40,557
Called up share capital not paid	-	811,000	-	811,000
Prepayments	136,377	93,872	132,734	81,418
Corporation tax	81,930	104,202	81,930	104,202
	<u>309,419</u>	<u>1,163,549</u>	<u>572,742</u>	<u>1,044,007</u>

All debtors are due within one year.

**15 Creditors: amounts falling due within one year**

	Group 2005 £	Group 2004 (restated) £	Company 2005 £	Company 2004 £
Bank overdraft	77,387	100,586	-	-
Trade creditors	247,631	220,738	233,688	166,074
Other taxes and social security costs	29,554	35,079	19,680	28,144
Other creditors	222,449	148,997	24,588	34,293
Accruals	41,280	95,492	24,500	79,000
Minority interests	176	176	-	-
	<u>618,301</u>	<u>601,068</u>	<u>302,456</u>	<u>307,511</u>

The bank overdraft is secured by a fixed and floating charge over the assets of Guildford Clinical Pharmacology Unit Limited.

**16 Financial instruments**

The Group's financial instruments comprise principally cash and current asset investments. The main purpose of these financial instruments is to finance the Group's operations.

The principal risk to the Group is liquidity and this is kept under review by the directors. The directors do not believe the Group has any significant currency risk or interest rate risk. The cash deposits are held in a mixture of short term deposits and current accounts at floating rates. The directors are of the opinion that there is no difference between the fair value and book value of financial instruments.

**17 Share capital**

	2005 £	2004 £
<i>Authorised</i>		
29,610,000,000 ordinary shares of 0.1p each	29,610,000	29,610,000
110,000,000 deferred shares of 4.9p each	5,390,000	5,390,000
	<u>35,000,000</u>	<u>35,000,000</u>
<i>Called up share capital</i>		
499,741,942 ordinary shares of 0.1p each	499,741	341,920
(2004 - 341,919,720 ordinary shares of 0.1p each)	5,297,948	5,297,948
108,121,391 deferred shares of 4.9p each	5,797,689	5,639,868
	<u>5,797,689</u>	<u>5,639,868</u>

Deferred shares do not carry voting rights and have no right to receive dividends. Deferred shareholders are entitled to receive the amount paid up or credited as paid up on their respective holdings of deferred shares only after there has been paid on each ordinary share the nominal amount paid up on such share plus a further £1m per ordinary share. The holders of the deferred shares shall not be entitled to participate further in any distribution of the assets or the capital of the Company.

**17 Share capital (*Continued*)**

On 15 September 2005, the Company issued 2,222,222 ordinary shares of 0.1p each at a premium of 1.25p per share for a consideration of £30,000 representing the underwriting commission payable upon entering in to an agreement with the Headstart Group of Funds under which Headstart will make available to the Company a committed share finance facility of up to £2,000,000.

On 15 September 2005, the Company issued 89,000,000 ordinary shares of 0.1p each at a premium of 0.9p per share for a consideration of £890,000.

On 10 October 2005, the Company issued 66,600,000 ordinary shares of 0.1p each at a premium of 0.9p per share for a consideration of £666,000.

The issued shares rank *pari passu* with existing shares.

*Share options*

At 31 December 2005, total share options outstanding under the Company's approved and unapproved share option plan are as set out below:

<b>Date of grant</b>	<b>Number of shares</b>	<b>Date from which options are first exercisable</b>	<b>Lapse date</b>	<b>Price per share</b>
24 March 2000	300,000	24 March 2002	23 March 2010	28p
7 December 2000	200,000	1 December 2002	30 November 2010	28p
5 December 2001	300,000	5 December 2002	4 December 2011	12p
25 July 2002	89,285	25 July 2002	24 July 2007	7p
25 November 2003	1,150,000	25 November 2003	24 November 2008	6p
13 February 2004	4,500,000	13 February 2004	13 February 2009	6p
21 December 2004	975,000	21 December 2004	21 December 2009	6p

On 10 October 2005 4,000,000 warrants were issued to J.M. Finn & Co to subscribe for 0.1p ordinary shares at an exercise price of 1p. These warrants are exercisable from 10 October 2005 to 10 October 2008.

On 10 October 2005 2,000,000 warrants were issued to E.C. Capital Limited to subscribe for 0.1p ordinary shares at an exercise price of 1.65p. These warrants are exercisable from 10 October 2005 to 10 October 2008.

On 10 October 2005 1,000,000 warrants were issued to Headstart Global Fund Limited to subscribe for 0.1p ordinary shares at an exercise price of 1.65p. These warrants are exercisable from 10 October 2005 to 10 October 2008.

On 10 October 2005 1,000,000 warrants were issued to Headstart Global Aggressive Fund Limited to subscribe for 0.1p ordinary shares at an exercise price of 1.65p. These warrants are exercisable from 10 October 2005 to 10 October 2008.

**18 Reserves**

<b>Group</b>	<b>Other reserve £</b>	<b>Share premium £</b>	<b>Profit and loss account £</b>
At 1 January 2005	242,308	9,173,181	(11,512,563)
Shares issued	-	1,428,179	-
Share issue costs written off (£30,000 non-cash)	-	(163,412)	-
Loss transferred to reserves	-	-	(2,140,716)
	<hr/>	<hr/>	<hr/>
At 31 December 2005	<b>242,308</b>	<b>10,437,948</b>	<b>(13,653,279)</b>
	<hr/>	<hr/>	<hr/>
<b>Company</b>		<b>Share premium £</b>	<b>Profit and loss account £</b>
At 1 January 2005		9,173,181	(9,788,395)
Shares issued		1,428,179	-
Share issue costs written off (£30,000 non-cash)		(163,412)	-
Loss transferred to reserves		-	(1,564,022)
		<hr/>	<hr/>
At 31 December 2005		<b>10,437,948</b>	<b>(11,352,417)</b>
		<hr/>	<hr/>

**19 Reconciliation of movements in equity shareholders' funds**

<b>Group</b>	<b>2005 £</b>	<b>2004 £</b>
Loss for the financial year	(2,140,716)	(1,388,026)
New shares issued	1,422,588	1,902,746
	<hr/>	<hr/>
(Decrease)/increase to equity shareholders' funds	(718,128)	514,720
Opening equity shareholders' funds	3,542,794	3,028,074
	<hr/>	<hr/>
Closing equity shareholders' funds	<b>2,824,666</b>	<b>3,542,794</b>
	<hr/>	<hr/>

**19 Reconciliation of movements in equity shareholders' funds (Continued)**

Company	2005 £	2004 £
Loss for the financial year	(1,564,022)	(1,276,468)
New shares issued	1,422,588	1,660,438
(Decrease)/increase to equity shareholders' funds	(141,434)	383,970
Opening equity shareholders' funds	5,024,654	4,640,684
Closing equity shareholders' funds	4,883,220	5,024,654

**20 Reconciliation of operating loss to net cash outflow from operating activities**

	2005 £	2004 £
Operating loss	(2,259,569)	(1,543,631)
Amortisation	119,119	92,460
Depreciation	8,132	4,947
Increase in stocks	(3,776)	(500)
Decrease/(increase) in debtors	831,858	(570,882)
Increase in creditors	40,608	256,705
Net cash outflow from operating activities	(1,263,628)	(1,760,901)

**21 Reconciliation of net cash flow to movement in net funds**

	2005 £	2004 £
Increase/(decrease) in cash in the year	18,422	(119,558)
Increase/(decrease) in liquid resources	175,095	(206,058)
Movement in net funds in the year arising from cash flows	193,517	(325,616)
Net funds at start of year	670,599	996,215
Net funds at end of year (note 22)	864,116	670,599



**22 Analysis of net funds**

	At start of year £	Cash flow £	At end of year £
Cash in hand	36,022	(4,777)	31,245
Bank overdraft	(100,586)	23,199	(77,387)
	<u>(64,564)</u>	<u>18,422</u>	<u>(46,142)</u>
Liquid resources	735,163	175,095	910,258
	<u>670,599</u>	<u>193,517</u>	<u>864,116</u>

**23 Commitments under operating leases**

As at 31 December 2005, the Company had annual commitments under non-cancellable operating leases as set out below:

Group and Company	Land and buildings 2005 £	Land and buildings 2004 £
Operating leases which expire:		
Within one year	19,000	9,500

**24 Related party transactions**

The following directors provided services on an arms length basis to the Group and the amounts charged were:

P W C Lomax	£12,544 (2004 - £8,195) Services through Lomax Pharmaceutical Consulting of which P W C Lomax is a partner The balance outstanding at 31 December 2005 was £Nil (2004 - £Nil).
K B Corbin	£961 (2004 - £Nil) Services through Nerine Trust Company Limited of which K B Corbin is a director The balance outstanding at 31 December 2005 was £Nil

**25 Going concern**

The directors have reviewed and amended the Company's plans for utilising its existing resources and believe that future funds available together with any potential licensing deal will be sufficient for the Group's purposes for a minimum of 12 months.

On this basis the directors consider it appropriate to prepare the financial statements on the going concern basis.

If a licensing deal, further fundraising or ongoing drug development programme are not successful then adjustments may be necessary to write down assets to their recoverable amounts, reclassify fixed assets and long term liabilities as current and provide for additional liabilities.

**26 Post balance sheet event**

On 14 February 2006 the Group acquired Sciencom Limited for £25,000, financed by the issue of 1,562,500 ReGen Therapeutics Plc ordinary shares of 0.1p each at 1.6p, the mid market closing price on 8 February 2006. ReGen has also agreed to pay additional consideration for the acquisition of £100,000 following the demonstration, to the reasonable satisfaction of ReGen, of the efficacy of a formulation in the form of clinically significant benefit.

**27 Prior year adjustment**

The Group has adopted FRS 25 "Financial instruments: disclosure and presentation" for the first time. The effect of the change in accounting policy to adopt the presentation requirements of FRS 25 was to reclassify non equity minority interests of £176 (2004 - £176) from equity to liabilities.